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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,965	06/20/2006	Ezio Bombardelli	2503-1189	7314

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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
12/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,965	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/2010 has been entered.

Applicant's amendment and 132 Declaration in the reply filed on 6/22/2010 are acknowledged, with the cancellation of Claims 3, 5, and 11-12. Claims 1, 2, 4, 6-10, 13, and 14 are pending. Claims 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 2, 4, 9, 13, and 14 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 9, 13, and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A1), in view of Bertini Curri et al (US 5,176,919), and further in view of Smith, III et al (US 2003/0069618).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 12/22/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third vasoactive agent, thus overlaps with the claimed range of 0.5-2%), 0.1-2.5% complex of Gingko biloba dimeric flavonoids with phospholipids (the second vasoactive agent, thus overlaps with the claimed range of 0.1-1%) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of Gingko biloba dimeric flavonoids with phospholipids, has the same activity as the dimeric Gingko biloba flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. Gingko biloba dimeric flavonoids are extremely potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, liens 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent visnadin, or the claimed amount of visnadin into the composition.

Bertini Curri et al teach pharmaceutical and cosmetic compositions comprising extracts of Ammi visnaga and Ammi majus containing visnadine (the same as visnadin) and/or visnadine-like coumarins and flavoncoumarols, or visnadine itself in purified form, for the cosmetic treatment of defects due to insufficient blood perfusion of the skin and of the subcutaneous adipose tissue, particularly for the treatment of precocious senile involution of the face and neck skin, cellulitis, cutaneous stretch marks, alopecias and similar conditions (col 2, lines 10-25). Bertini Curri et al also teach the composition is a cream, ointment, gel or lotion (claim 5). Bertini Curri et al further teach a gel containing 1% of visnadine as active principle (1 g of visnadine out of a 100 g gel) (thus falls into the claimed range of 0.05-2% for the first vasoactive agent).

Smith, III et al teach that in the condition of cellulite, a reduction in local blood supply to the tissues results from increased pressure on the tissues due to upwards pressure from excess underlying adipose tissue, as well as, from deposition of plaque-like substances that clog the arterioles and venous capillaries. The increased blood perfusion flushes the capillaries and arterioles, resupplying the tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage [0049].

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the a vasoactive agent visnadine from Bertini Curri et al to treat cellulite in Di Pierro since Bertini Curri et al teach visnadine is used for cosmetic treatment of defects due to insufficient blood perfusion and as evidenced by Smith et al, cellulite is due to a reduction in local blood supply and deposition of plaque-like substances that clog the arterioles and venous capillaries. Therefore, one of ordinary skill in the art would have been motivated to use the vasoactive agent visnadine from Bertini Curri et al to let the increased blood perfusion

flushes the capillaries and arterioles, and resupplying the cellulite tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage so as to enhance the treatment of cellulite of Di Pierro. It would be obvious for one of the ordinary skill in the art to exclude the components ethylximeninate, and standardized Coleus forskolli extract from Di Pierro, as they are only optional as taught by Di Pierro. Furthermore, a cream, a gel or milk is allowed to contain variety of components with different activities.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Bertini Curri et al is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "However, starting from the DI PIERRO composition, one skilled in the art would not have contemplated selecting three active ingredients namely (a) escin/beta-sitosterol, (b) Gingko biloba dimeric flavonoids and (c) Centella asiatica triterpenes, and combining the same with different vasoactive components (visnadine or esculoside) to prepare the present anti-cellulite composition" (page 9, 1st paragraph). Applicant also argues that "Looking at the file history of the US counterpart of DI PIERRO(U.S. Patent No. 7,476,392),

which shares the same assignee as the present application, only the composition (a) + (b) +(c) + (d) ethyl ximeninate +(e) standardized coleus forskolii extract displays synergism. A signed declaration made by DI PIERRO that was presented in this US counterpart, which explains this synergism, is provided in the appendix of this amendment" (page 9, 2nd paragraph). Applicant further argues that "One would not have expected these synergistic properties as demonstrated in the declaration by the present inventor, since DI PIERRO teaches that such ingredients are active only in combination with the other ingredients (d) and (e). Indeed, one would have expected that a selection of only three of the ingredients from the whole combination of (a) to (e) would have disrupted the synergism, and, consequently, such a selection would have rendered the composition unsatisfactory for the intended purpose of DI PIERRO" (page 10, 3rd paragraph).

This is not found persuasive. In Di Pierro reference, DI PIERRO teaches a composition comprising a) complex of escin/beta-sitosterol with phospholipids, b) complex of Gingko biloba dimeric flavonoids with phospholipids, c) complex of Centella asiatica triterpenes with phospholipids, and optionally one or both of: d) ethylximeninate, and e) standardized Coleus forskolli extract (page 10, 1st paragraph). Therefore, components d) ethylximeninate, and e) standardized Coleus forskolli extract are only optional, and they are not required for synergistic effect.

Applicant argues that "Thus, contrary to the presently claimed invention, DI PIERRO neither discloses nor suggests a synergistic composition based on the claimed three active ingredients: (a) a complex of escin/beta-sitosterol with phospholipids, (b) a complex of Gingko biloba dimeric flavonoids with phospholipids and (c) a complex of Centella asiatica triterpenes with phosopholipids" (page 9, 3rd paragraph). Applicant also argues that "The appendix of this

amendment also includes a Declaration Under Rule 132 by the named inventor of the present application, Dr. Ezio Bombardelli. This declaration is further to the one filed May 30, 2007, and it provides additional experimental evidence that demonstrates the synergistic effect exerted by the active ingredients of the claimed composition" (page 9, last paragraph). Applicant further argues that "That is, the data presented in the new declaration shows a "more than additive" anti-cellulite effect produced by two compositions according to the claimed invention, i.e., the composition described in example 5 of the specification and the same composition with esculoside in place of visnadin" (page 10, 2nd paragraph).

This is not found persuasive. The Declaration under 37 CFR 1.132 filed on 6/22/2010 is insufficient to overcome the 103 rejection as set forth in the last Office Action because: The Groups 6 and 7 in the Declaration Under Rule 132 filed on 6/22/2010 which showed unexpected result has a different scope than what is being claimed right now. Group 6 contains 0.3% visnadin, 0.4% amentoflavone, and 1.0 centella asiatica extract. Group 7 contains 0.5% esculoside, 0.4% amentoflavone, and 1.0 centella asiatica extract. However, none of the claims recites a composition like that, and there is no description in the Specification for a composition like that. Therefore, the unexpected result does not commensurate with what is being claimed.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655